510(k) Summary K112078

MAR 19 2012

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 07/15/2011

1. Submission Sponsor

	Submitter
Name	MARUCHI
Address	1720-26 Medical Industry Complex Bldg. No. 2-208, Taejang-dong, Wonju-si, Gangwon-do, 220-120, South Korea
Phone	Tel: +82-33-734-0330
Fax	Fax: +82-33-746-2804

2. Submission Correspondent

LK Consulting Group
951 Starbuck St. Unit J,
Fullerton, CA 92833
Priscilla Chung
Phone: 714-869-3080 Fax: 714-409-3357
Email: info@LKconsultinggroup.com

3. Device

- Trade Name: ENDOCEM MTA (Mineral Trioxide Aggregate)
- Common Name: Root filling material
- Classification Name: Root canal filling resin
- Classification regulation: 21 CFR 872.3820
- Product Code: KIF

4. Predicate Device

MTA MATERIAL (K981620), Dentsply International

5. Description:

This product is designed for vital pulp therapies like direct pulp capping treatment. It effectively prevents secondary infection as well as pulp irritation.

6. Indications for use:

- A root-end filling material
- For the repair of root canals as an apical plug during apexification
- For repair of root perforations during root canal therapy
- As a consequence of internal resorption
- As a pulp capping material
- For the filling of pulpotomy of deciduous tooth

7. Safety and Effectiveness:

ENDOCEM MTA (Mineral Trioxide Aggregate) has similar physical and biocompatible properties, and demonstrates comparable performance specifications to MTA MATERIAL (Predicate device). In addition, ENDOCEM MTA (Mineral Trioxide Aggregate) has a comparable delivery system to MTA MATERIAL.
The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that ENDOCEM MTA (Mineral Trioxide Aggregate) is safe, effective and substantially equivalent to the predicate device.

8. Physical Characteristics

The following properties were tested for the device according to ISO 6876 and all the results met the test criteria.

- ISO 6876 - Setting time, Solubility, Dimensional change following setting and Radiopacity

9. Conclusion

Based on the information provided in this premarket notification, ENDOCEM MTA (Mineral Trioxide Aggregate) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 19 2012

MARUCHI
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street, Unit J
Fullerton, California 92833

Re: K112078
Trade/Device Name: ENDOCEM MTA (Mineral Trioxide Aggregate)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: February 22, 2012
Received: February 28, 2012

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112078

Device Name: ENDOCEM MTA (Mineral Trioxide Aggregate)

Indications for Use:

- A root-end filling material
- For the repair of root canals as an apical plug during apexification
- For repair of root perforations during root canal therapy
- As a consequence of internal resorption
- As a pulp capping material
- For the filling of pulpotomy of deciduous tooth

Prescription Use __√__ **AND** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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